K132276

Section 5 510(k) Summary

The following is a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 for the Sterile Empty Glass Container.

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H2 275 North Field Drive Lake Forest, IL. 60046
Phone number	(224) 212-6162
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator No. 9063339)
Name of contact person	Abigail Ferguson
Date prepared	July 15, 2013
Name of device	
Trade or proprietary name	Sterile Empty Glass Container
Common or usual name	I.V. Container
Classification panel	Class II
Regulation	21 CFR 880.5025
Product Code(s)	KPE
Legally marketed device(s) to which equivalence is claimed	Empty Evacuated Container (Pre-amendment Device)
	The changes addressed in this submission include: • The name of the product will be changed from "Empty Evacuated Container" to "Sterile Empty Glass Container". • The current Empty Evacuated Container label indicates the product is to be used in admixing compatible medications as well as the use for the collection of blood. The proposed Sterile Empty Glass Container will only be indicated for admixing of compatible medications. The product's use for the collection of blood will be removed from the label. • A new Instructions for Use document has been created and will be included as an enclosure with the product.

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	• The washing procedure for the EPDM rubber stopper has been moved from Hospira to the stopper vendor, Datwyler. Additionally, Datwyler has instituted a revised procedure. A comparison of the wash procedures is provided in **Section 11 Device Description**.
Device Description	The Sterile Empty Glass Container consists of a Type II glass container in 250 mL, 500 mL and 1000 mL sizes, a 28 mm EPDM rubber stopper, an aluminum overseal that secures the stopper to the glass container, and a unit label with an integrated hangar. The device is sterile and non-pyrogenic.
Intended Use of the Device	The Hospira Sterile Empty Glass Container is intended to be used for admixing compatible medications

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**Preamendment**	**Proposed**
Indications for Use	For use in admixing compatible medications and collection of blood.	The Hospira Sterile Empty Glass Container is indicated for admixing compatible medications.
Materials of Construction	Type II Glass Container 28 mm EPDM Rubber Stopper Aluminum Overseal Unit Label with integrated Hanger	Same
Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for the Sterile Empty Glass Container meet the applicable material test requirements of ISO 10993.	Same
Summary of Performance Testing	Performance testing was conducted to ensure the device performs as intended. All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.	Same

Conclusion

The Sterile Empty Glass Container meets the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the Empty Evacuated Container, which is a preamendment device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

Hospira, Incorporated
C/O Ms. Abigail Ferguson
Associate, Regulatory Affairs
275 Field Drive
LAKE FOREST ILLINOIS 60045

Re: K132276
Trade/Device Name: Sterile Empty Glass Container
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: October 11, 2013
Received: October 16, 2013

Dear Ms. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary FBVlner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K132276

Device Name: Sterile Empty Glass Container

Indications for Use: The Hospira Sterile Empty Glass Container is indicated for admixing of compatible medications.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Richard C. Chapman
Date: 2013.11.20
17:30:14 -05'00'